IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

CYCLOPS VAPORS 2, LLC, *et al*.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	CIVIL ACT. NO. 2:16cv556-MHT
	)	(WO)
UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al*.,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OPINION and ORDER

INTRODUCTION

On July 8, 2016, the plaintiffs filed this declaratory judgment action against the United States Food and Drug Administration ("FDA"), Robert Califf and Sylvia Burwell ("collectively the government defendants") challenging the defendants' implementation of a final rule related to e-cigarette devices and e-liquids. The plaintiffs distribute e-cigarette devices and e-liquids, and challenge the FDA's "Deeming Rule" which places these products under the FDA's authority to regulate pursuant to the Tobacco Control Act, 21 U.S.C. § 387a(b).[1] According to the plaintiffs, the defendants' Deeming Rule will subject their products to "the premarket approval, reporting, recordkeeping, inspection, labeling,

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[1] 21 U.S.C. § 387a(b) provides as follows:

> This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, and *to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter*.

21 U.S.C. § 387a(b) (emphasis added).

manufacturing, testing and other requirements" of tobacco products, and will "severely and unnecessarily burden" their businesses. (Doc. # 1 at 7, ¶ 30-31). The plaintiffs ask the court to declare the Deeming Rule "an arbitrary and capricious regulatory system" and vacate the rule. (*Id*. at 16.) The court has jurisdiction of this action pursuant to the Administrative Procedures Act, 5 U.S.C. § 500 *et seq*., the Administrative Procedure Act Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq*., the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the court's federal question jurisdiction, 28 U.S.C. § 1331.

On December 13, 2016, the parties filed a joint motion for entry of a briefing schedule asserting that because this case is governed by the Administrative Procedures Act, "it will be resolved on the basis of the administrative record complied by the agency." (Doc. # 15 at 1, ¶ 2. On December 19, 2016, the court granted the parties' motion and entered a scheduling order setting forth deadlines for filing dispositive motions, cross motions and responses. (Doc. # 20). On February 1, 2017, the plaintiffs filed a motion for summary judgment. (Doc. # 21). On February 10, 2017, the Campaign for Tobacco-Free Kids filed a motion for leave to file an amicus brief (doc. # 25) which the court granted (doc. # 28).

On March 1, 2017, the defendants filed a consent motion for an extension of time to respond to the plaintiffs' motion for summary judgment (doc. # 29) which the court granted. (Doc. # 30). On May 1, 2017, the parties filed another joint motion to amend the scheduling order (doc. # 31) which the court also granted. (Doc. # 32).

On July 24, 2017, the American Academy of Pediatrics, the American Cancer Society

Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco-Free Kids, and the Truth Initiative (collectively "the Public Health Intervenors") filed a motion to intervene pursuant to FED.R.CIV.P. 24. (Doc. # 33). The Public Health Intervenors seek to intervene as a matter of right under FED.R.CIV.P. 24(a)(2) or alteratively, permissibly under FED.R.CIV.P. 24(b)(1). The plaintiffs oppose the motion to intervene (doc. # 67) arguing that the motion is premature and untimely. The plaintiffs also argue that the Public Health Intervenors have not demonstrated that the government defendants would not adequately defend their rights. The government defendants have filed a response in which they reserve the right to oppose intervention but suggest that the motion to intervene is premature. (Doc. # 65).

Also pending before the court is the parties' joint motion to stay the case and vacate the briefing schedule (doc. # 54) pending the outcome of the appeal of *Nicopure Labs LLC v. FDA*, 266 F. Supp. 3d 360 (D.C. 2017) *appeal docketed* No. 17-5196 (D.C. Cir. Aug. 31, 2017) which addresses the very issues raised in this case.

Pursuant to 28 U.S.C. § 636, this case is referred to the undersigned for consideration and disposition or recommendation of all pretrial matters. (Doc. # 19). The court heard oral argument on the motion to intervene on August 10, 2017. After careful consideration of the motion to intervene, and the briefs filed in support of and in opposition to the motion, the court concludes the motion to intervene (doc. # 33) is due to be granted. The court further concludes that the joint motion to stay the case (doc. # 54) is due to be granted and the

motion to vacate the briefing schedule is due to be denied as moot.

DISCUSSION

A. Motion to Intervene

The crux of this litigation involves the "Deeming Rule" created by the FDA which determined that e-cigarettes, e-liquids, and other related products were deemed tobacco products and subject to FDA regulation. According to the Public Health Intervenors the "Deeming Rule" is necessary to permit the FDA to regulate flavored e-cigarettes and products as well as marketing strategies aimed at young people. The Public Health Intervenors assert that "[s]etting aside the Deeming Rule, as Plaintiffs request, would have a direct adverse effect on public health, particularly among youth." (Doc.# 33 at 7[2]). In opposition to the motion to intervene, the plaintiffs assert that intervention by the Public Health Intervenors at this juncture would "unnecessarily encumber the litigation of the issues raised in this lawsuit." (Doc. # 67 at 6). The court disagrees.

"Intervention under Rule 24 can be either as of right or permissive." *Salvors, Inc. v.Unidentified Wrecked & Abandoned Vessel*, 861 F.3d 1278, 1293 (11th Cir. 2017). FED.R.CIV.P. 24(a) allows a third party to intervene as a matter of right if four requirements are met:

(1) [the] application to intervene is timely; (2) [the applicant] has an interest

[2] Based on the manner in which the Intervenors formatted their motion, there is an inconsistency between the document's page numbers and the page numbering created by the court's electronic case management filing system. For ease of reference, the court references the system's page numbering when quoting from the parties' documents.

> relating to the property or transaction which is the subject of the action; (3) [the applicant] is so situated that disposition of the action, as a practical matter, may impede or impair his ability to protect that interest; and (4) [the applicant's] interest is inadequately represented by existing parties to the suit.

Purcell v. BankAtlantic Financial Corporation, 85 F.3d 1508, 1512 (11th Cir. 1996).

The court need not determine whether the Public Health Intervenors have a right to intervene under FED.R.CIV.P. 24(a) because the court concludes that even if the Public Health Intervenors were not permitted to intervene as a matter of right, they should be permitted to intervene pursuant to FED.R.CIV.P. 24(b). "If there is no right to intervene under Rule 24(a), it is wholly discretionary with the court whether to allow intervention under Rule 24(b)." *Purcell*, 85 F.3d at 1513. The court may permit permissive intervention when the motion is timely, and "if the intervenor's claim or defense and the main issue of the cause have a common question of fact." *Id*.

The plaintiffs argue that the Public Health Intervenors' motion to intervene is untimely because it was filed more than a year after the complaint was filed and more than six months after the plaintiffs' motion for summary judgment was filed. *See* Doc. # 67 at 3. While the plaintiffs filed their motion for summary in February 2017, they thereafter consented to extensions of the deadlines related to their motion. *See* Docs. # 29 and 31. Based on the extensions, the defendants' response to the plaintiffs' motion for summary judgment was not due until August 2, 2017 and the defendants' cross-motion for summary judgment was not due until September 5, 2017. The Public Health Intervenors filed their

motion to intervene on July 24, 2017.[3] Consequently, the motion for summary judgment was not under submission at the time the Public Health Intervenors filed their motion to intervene. Moreover, the Public Health Intervenors assert that it was the joint motions for extensions of time that led them to believe that the parties might not adequately defend the Deeming Rule. Undoubtedly, the Public Health Intervenors' motion is premised on their fear that the government will not "adequately defend the Deeming Rule and may seek to weaken or rescind it." (Doc. # 33 at 13). While this fear is speculative, it in no way minimizes the fact that the Intervenors would be practically and substantially affected by rescission of the rule.

Moreover, neither the plaintiffs nor the government defendants have demonstrated that they would be prejudiced by allowing the Public Health Intervenors to intervene and participate in this litigation at this juncture. *See Salvors, Inc.*, 861 F.3d at 1294 ("the original parties to the action have not claimed any prejudice stemming from [the] claimed delay"). Consequently, the court concludes that the Public Health Intervenors' motion is timely based on the procedural history of this case.

FED.R.CIV.P. 24(b)(1)(B) permits intervention when the party seeking to intervene "has a claim or defense that shares with the main action a common question of law or fact." It is clear the Public Health Intervenors have an interest and a claim in the maintenance of the Deeming Rule and the impact of rescission of that rule on public health and its

[3] The Public Health Intervenors previously filed a motion to file an *amicus curie* brief within ten days of the plaintiffs' motion for summary judgment placing all parties on notice that they had an interest in this litigation. *See* Doc. # 25.

organizations. Thus, the Public Health Intervenors easily satisfy this element for permissive intervention.

For the reasons as stated, the court concludes that the Public Health Intervenors' motion was timely and none of the parties have been or will be prejudiced by permitting intervention. Consequently, the court concludes that the requirements of FED.R.CIV.P. 24(b) have been met and the motion to intervene is due to be granted.

B. Motion to Stay

On July 31, 2017, the parties filed a joint motion to stay this case and vacate the briefing schedule (doc. # 54), because an analogous case with identical issues was pending in the District Court of the District of Columbia. (*Id*.) On September 28, 2017, the parties filed a joint notice informing the court that the case was now on appeal in the United States Court of Appeal for the District of Columbia Circuit. *See Nicopure Labs LLC v. FDA*, 266 F. Supp. 3d 360 (D.C. 2017) *appeal docketed* No. 17-5196 (D.C. Cir. Aug. 31, 2017). Because the case on appeal is very similar to the case at bar, a decision from that appellate court will likely inform and impact resolution of this case. Thus, the parties jointly requested a stay to conserve litigation costs and judicial resources. After careful consideration, the court concludes that it is appropriate to stay resolution of this matter pending a decision in *Nicopure Labs LLC, supra*.

CONCLUSION

Accordingly, for the reasons as stated and for good cause, it is ORDERED as follows:

1. That the motion to intervene (doc. # 33) be and is hereby GRANTED and the American Academy of Pediatrics, the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco-Free Kids, and the Truth Initiative be and are hereby PERMITTED to intervene as defendants in this action;

2. That the parties' joint motion to stay case (doc. # 54) be and is hereby GRANTED and that this case be and is hereby STAYED pending a decision by the United States Court of Appeal for the District of Columbia Circuit in *Nicopure Labs LLC v. FDA*, 266 F. Supp. 3d 360 (D.C. 2017) *appeal docketed* No. 17-5196 (D.C. Cir. Aug. 31, 2017);

3. The parties are DIRECTED to file a joint status report within forty-five (45) days of the date of a decision issued by the United States Court of Appeal for the District of Columbia Circuit in *Nicopure Labs LLC v. FDA*, 266 F. Supp. 3d 360 (D.C. 2017) *appeal docketed* No. 17-5196 (D.C. Cir. Aug. 31, 2017); and

4. That the motion to vacate the briefing schedule (doc. # 54) be and is hereby DENIED as moot.

Done this 22nd day of March, 2018.

/s/Charles S. Coody
CHARLES S. COODY
UNITED STATES MAGISTRATE JUDGE